

Certificate of Analysis

STERINIX STBD | BASED ON THE MANUFACTURER'S COA

PRODUCT SPECIFICATIONS

Product / Brand code	STERINIX Bowie-Dick Test Pack / STBD
Issued by / Source report	GLOBAL BIOTECH / QS2026080801
Lot / Expiration date	260808 / 2029-08-07
Size (source COA)	115 × 125 mm
Application / Indicator type	Pre-vacuum steam sterilizer performance check / Type 2
Label-declared standards	ISO 11140-1 (general requirements); ISO 11140-4 (Bowie-Dick alternative test indicators for steam penetration)
Test conditions	121°C / 15 min; 134°C / 3.5 min
Color response (label)	Blue to uniform black; residual blue / uneven change = fail
Storage (label)	10-30°C; 30-80% RH; keep dry and protect from sunlight
Use / Contents	Single use / 1 test per pack

LOT TEST RESULTS

B1, B2 and B3: three repetitions per condition. Temperature depression of the 7 kg standard test package is reported below.

Temp. (°C)	Time (min)	Cycle	Repeats	Color change	Pre-test ¹ (°C)	Pro-test ¹ (°C)
121	15	B1	3	Blue to black	0.6	0.7
121	15	B2	3	Blue to black	0.5	0.7
121	15	B3	3	Blue to black	0.6	0.8
134	3.5	B1	3	Blue to black	0.5	0.6
134	3.5	B2	3	Blue to black	0.4	0.6
134	3.5	B3	3	Blue to black	0.5	0.6

¹ Source terms retained. "Pro-test" is not defined in the source; individual repeat measurements are not supplied.

MANUFACTURER CONCLUSION

Indicators changed from blue to black. Temperature depression of the 7 kg standard test package was less than 1°C, reported as consistent with the no-fault condition.

STANDARDS & DOCUMENT BASIS

ISO references and basic specifications are transcribed from the product label; lot results are from manufacturer COA QS2026080801. The results shown do not, by themselves, establish full conformity with ISO 11140-1 or ISO 11140-4.

This distributor-issued summary is not independent testing by GLOBAL BIOTECH or an accredited laboratory report. Results apply only to the stated lot and conditions. The original manufacturer COA is retained on file.

Authorized by: Andy Jung / GLOBAL BIOTECH

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